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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,033	10/21/2003	Zongqin Xia	HASEL-65949	7549

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1655

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,033

Applicant(s)

XIA ET AL.

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 20, 2005 has been entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. In the reply filed on May 24, 2004 applicant elected without traverse Group III, claims 5-8.
3. Claims 1-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 24, 2004.
4. Claims 5-8 are examined on the merits.
5. The declaration of Dr. Daryl Rees has been considered.

Claim Rejections - 35 USC § 112

6. Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claims are enabled for the treatment of Parkinson's disease in humans using smilagenin because the disease models used show

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credible evidence that treatment of Parkinson's disease using smilagenin would be successful.

Thus, the method of treatment claimed could be carried out without undue experimentation.

However, applicant only shows results using *in vitro* cell cultures and using rat models. While these models may be effective for screening possible anti-Parkinson's candidates, these models are not necessarily predicative of results in human patients. The art teaches that effective treatment of Parkinson's disease in rat models does not necessarily predict successful treatment in humans due to differences between the species. The art recommends using primate models as the most clinically relevant model for predicting successful treatment in humans (see Eberling et al. Experimental Neurology (2002), vol. 178, pp. 236-242, specifically page 240, first column and Emborg; Journal of Neuroscience Methods (2004), vol. 139, pp. 121-143, specifically page 134, first column). In order to test the effectiveness of Parkinson's treatments, Eberling and Emborg indicate that non-human primates should be used as animals models after testing has been performed on rat models. Applicant does not perform any testing on humans or non-human primates; thus, a person of ordinary skill in the art would be forced to carry out further testing to determine if the smilagenin is actually able to treat Parkinson's disease in humans as claimed.

Terminal Disclaimer

7. The terminal disclaimers filed on July 20, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. No. 6,812,213, US Pat. Appl. No. 10/109,095, US Pat. Appl. No. 10/109,204, US Pat. Appl. No. 10/336,176, US Pat. Appl. No. 10/472,892, and US Pat. Appl. No. 10/189,024 have been reviewed and are accepted. The terminal disclaimers have been recorded.

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8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



8-22-05

Susan D. Coe
Primary Examiner
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